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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------|
| 10/749,061 | 12/30/2003 | Geoffrey H. Willis | GUID-034 | 7376 |
| 36154 | 7590 | 11/01/2005 | | |
| LAW OFFICE OF ALAN W. CANNON 834 SOUTH WOLFE ROAD SUNNYVALE, CA 94086 | | | EXAMINER KILKENNY, PATRICK J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3732 | |
| DATE MAILED: 11/01/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/749,061 | WILLIS, GEOFFREY H. | |
| | Examiner | Art Unit | |
| | Patrick J. Kilkenney | 3732 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/3/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-11, 15-22, 24-30, 32, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckman Jr. et al. (5,484,391). Buckman Jr. et al. discloses a device capable of manipulating and positioning a heart, absent clinically relevant hemodynamic instability, with an inflatable annular member (Fig. 6, #82) with a central opening (Fig. 7, space through which 76 passes into 82), and an organ-contacting surface (Fig. 6, #86). The annular member can be inflated with liquid or gas (Column 9, lines 41-42). The heart-contacting surface is made of a cushioning compliant material (Claim 4), specifically a foam rubber (Column 6, lines 64-67). This contacting material is configured to conform to and diffuse suction exerted on the organ (Column 6, lines 55-59). There is also vacuum source coupled to the positioning element and a vacuum distribution element associated with the annular member configured to diffuse suction exerted on the heart (Fig. 7, #80; Fig. 8, #120; Column 11, lines 17-22). The vacuum distribution element (Fig. 8, #120) is made of a foam rubber since it is an indentation of the end of the contacting member, (Fig. 8, #112), which is analogous to heart contacting member (Fig. 1, #16 and Column 11, lines 4-6). There is a position element (Fig. 6,

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#76), compromising a lumen, coupled to a vacuum source (Fig. 7 #'s 80 and 90; Column 9, lines 43-45) and to the inflatable member and a regulator for controlling the vacuum flow (Fig. 7, #92; Columns 9-10, lines 67-3). The inflatable annular member is coupled to the positioning element with a series of attachment means (Fig. 7, #'s 84A and 104), which are made of plastic as disclosed for all embodiments of the heart contacting members (Column 6, lines 51-53), and silicone material. Also disclosed is a spring element system (Figs. 9-11, #'s 144 and 156 specifically) associated with the positioning element that allows axial movement of the inflatable annular member (Column 11, lines 36-38). There is also a sheath of inner and outer sleeves (Fig. 10, #'s 146 and 156) that can retain the deflated device for insertion into the body cavity Fig. 11, # 146).

Buckman Jr. et al. also discloses methods for manipulating and positioning the heart, possibly during the absence of clinically relevant hemodynamic instability, with the device described above by introducing the device into the body cavity via a thoracotomy (Column 15, lines 12-14 and 34-48). The device is capable of being inflated with gas or liquid (Column 9, lines 41-42), and a vacuum source can be operatively coupled to the positioning element (Column 10, lines 27-33, 50-53, and 58-61). Again, a sheath is disclosed for inserting the device in the body cavity (Fig. 11, #146) and the vacuum exerted on the organ is diffused by a vacuum distribution element and the surface conforms to the heart surface (Fig. 8, #120).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. in view of Heaven et al. (5,337,754). Buckman Jr. et al. discloses the claimed invention with the exception of the seams of the inflatable annular member being positioned on the interior of the member. Heaven et al. discloses a medical retractor with an inflatable member that utilizes internal seams yielding less traumatic surfaces on the exterior (Column 6, lines 3-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Buckman Jr et al. with internal seams, as taught by Heaven et al., which would result in a less traumatic surface being applied to the heart.

Claims 12-14, 23, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. in view of Peng et al. (6,506,149). Buckman Jr. et al. discloses the claimed invention except for the attachment means comprising a flexible linkage system or a ball and socket mechanism that allows sufficient vertical and lateral movement of the inflatable annular member. Peng et al. discloses a heart manipulator that has an attachment means comprising a flexible linkage system (Fig. 1, #4C) and a ball and socket mechanism (Fig. 30, # 154) that allows vertical and lateral

movement of the annular member. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the manipulator device of Buckman Jr. et al. with an attachment means comprising a flexible linkage system or a ball and socket mechanism, as taught by Peng et al., so that the organ manipulator device can be positioned correctly on the heart despite the orientation of the positioning element.

Buckman Jr. et al. also does not disclose a securing means and a method for securing the device to a stationary object. Peng et al. discloses a heart manipulator capable of, and a method for, securing the device to a stationary retractor (Fig. 1, 4A and Column 10, lines 24-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the manipulator device of Buckman Jr. et al. with a means and method for securing the manipulator device to a stationary object, as taught by Peng et al., since it is ideal to have retractor systems secured during any type of medically related operational procedure.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. Buckman Jr. et al. discloses the claimed invention with the exception of the method of applying 100 mmHg to 400 mmHg of vacuum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a vacuum force in the given range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. in view of Taylor et al. (5,906,607). Buckman Jr. et al. discloses the claimed method with the exception of performing a coronary artery bypass on the organ. Taylor et al. discloses a coronary artery bypass procedure on a heart being stabilized with a vacuum source retractor (Fig. 4). Furthermore, Taylor et al. discloses in the background and summary of their invention the benefits of using vacuum retractors for performing surgeries involving block coronary vessels. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Buckman Jr. et al. with a coronary bypass procedure, as taught by Taylor et al., because coronary bypass procedures are among the most common heart surgeries that require manipulation of the heart, ideally while still beating.

Claims 36-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al. Buckman Jr. et al. discloses the claimed invention, as described above, with the exception of kit with a plurality of devices and instructions for using the device. The examiner takes Official Notice that it is obvious to provide instructions within a device kit to enable correct utilization of the device. Therefore, it would have been obvious to provide instructions in a kit along with the device of Buckman Jr. et al., and it would have been obvious to provide a plurality of organ manipulation devices (subcombinations) in the kit (device/combination) since it has been held that mere duplication of the essential working parts of a device (i.e. the kit) involves only routine skill in the art. *St. Regis Paper Co. v. Bernis Co.*, 193 USPQ 8.

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Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buckman Jr. et al., as applied to claim 35 above, and further in view of Peng et al. Buckman Jr et al. discloses the claimed invention with the exception of a securing means for securing the device to a stationary object. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the manipulator device of Buckman Jr. et al. with a securing means, as taught by Peng et al., so that the organ manipulator device can effectively hold the retracted organ in desired position without the aid of a person during an operational procedure.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick J. Kilkenny whose telephone number is (571)272-8684. The examiner can normally be reached on Mon-Fri, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PJK



Patrick J. Kilkenny
Art Unit 3732
October 26, 2005

10/26/05


Carl E. O'Connor
Primary Examiner